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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,865	04/16/2004	Edgar Hommann	34206/US	8185

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EXAMINER

GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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02/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/825,865	Applicant(s) HOMMANN ET AL.	
	Examiner ANDREW M. GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. This office action is in reply to the response filed on 11/20/2007.
2. In the reply, the Applicant amended claim 1.
3. Thus claims 1-16, 18 are pending for examination.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3-7, 10-11, 13-16, and 18 rejected under 35 U.S.C. 102(b) as being anticipated by Mulhauser et al (5919167). Mulhauser et al discloses an injection device (Fig 1-2) comprising a capacitor as an energy storage device (126; col 5, Ins 30-50; Fig 7), wherein the at least one capacitor receives its charge from an external charging device removably coupled to the injection device (see discussion below in response to arguments); a reservoir housing (26) a medicament; a drive system (84); wherein the drive system remains operable for expelling a dosage after the charging device has been removed by discharging the charge from the external charging device (see

Response to Arguments below); a threshold value detector (col 5, lns 30-50) coupled to the capacitor; a charge indicator being a voltmeter operably coupled to the capacitor (126; col 5, lns 30-50; Fig 7); a processor (122); at least one of a memory and a signal output device (col 5, lns 30-50), said at least one of the memory and the signal output device supplied with current from the at least one capacitor (col 5, lns 30-50); an electronic system includes sensing elements (126; col 5, lns 30-50; Fig 7); further including control/processing elements and display elements capable of calculating and displaying the number of injections that can be performed based upon the power source (126; col 5, lns 30-50; Fig 7; wherein the user selected number of charges indicates that the controller can select and determined the number of charges, ie injections, that can be performed); the capacitor being rechargeable (126; col 5, lns 30-50; Fig 7).

6. Claims 1, 3, 9, 11-13, 16, 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Avarhami et al (6708060). Avarhami et al discloses an injection device (Fig 1a, b) comprising a duplex capacitor as an energy storage device (col 18, lns 19-23; col 20, lns 47-55; col 21, lns 41-49); wherein the at least one capacitor receives its charge from an external charging device removably coupled to the injection device (see discussion below in response to arguments); a reservoir housing (Fig 1a, b; 40) a medicament; a drive system (Summary); wherein the drive system remains operable for expelling a dosage after the charging device has been removed by discharging the charge from the external charging device (see Response to Arguments below); an electronic system including inductive charging elements (col 18, lns 19-23; col 20, lns

47-55; col 21, Ins 41-49; Fig 9); the capacitor being rechargeable (216); and an electronic system includes sensing elements (Summary).

7. In reference to claim 18, Avarhami et al discloses an injection system for injecting a medicament into a body (Fig 1a, b), the injection system comprising: an injection device comprising a reservoir housing (Fig 1a, b; 40) the medicament and a drive system (col 3, Ins 8-37) for expelling a dosage of the medicament from the reservoir; and at least one capacitor (216) for powering the drive system for performing at least one injection, the at least one capacitor providing the sole electric power source (216; col 21, Ins 26-49; Fig 9) for the injection device; and a charging device (power source 212; capable of being a battery 52 that is fully capable of being removably replaced when power is exhausted from it by a new battery) capable of removably coupling with the injection device for charging the at least one capacitor (col 21, Ins 26-49; wherein the Examiner notes that the capacitor (216) provides the sole electric power to the injection device during use. The removably coupled power source, ie – battery, only powers, or charges, the capacitor (Fig 9) when the switch (214) is closed. The capacitor discharges causing current to flow to electrodes (120) on skin that create an iontophoretic electric field driving an active medical substance from reservoir patch (74) into the patient.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3767

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mulhauser et al. Mulhauser et al discloses the invention substantially as claimed except for expressly disclosing that the capacitor is made out of gold. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the capacitor as taught by Jess et al with a gold capacitor since it was well known in the art that capacitors are made out of gold material. The Examiner further notes the rejection of claim 2 could also be made for the other prior art references discussed above.

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mulhauser et al in view of Portner et al (4360019). Mulhauser et al discloses the invention substantially as claimed except for expressly disclosing a DC/DC converter operably coupled to the at least one capacitor. Portner et al teaches that it is known to have a DC/DC converter operable coupled to the at least one capacitor (col 9, lns 13-15) for the purpose of charging the capacitor to a voltage matching the required voltage from the motor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the capacitor as taught by Mulhauser et al with the DC/DC converter as taught by Portner et al for the purpose of the purpose of charging the capacitor to a voltage matching the required voltage from the drive

member. The Examiner further notes the rejection of claim 8 in view of Portner et al could also be made for the other prior art references discussed above.

Response to Arguments

11. Applicant's arguments filed 5/24/2007 have been fully considered but they are not persuasive.

12. The Applicant argues that:

i. Mulhauser et al fails to disclose at least one capacitor receiving a charge from an external charging device removably coupled to the injection device.

ii. Avarhami et al fails to disclose at least one capacitor receiving a charge from an external charging device removably coupled to the injection device and wherein the at least one capacitor is the sole electric power source for the injection device.

13. In response to the Applicants argument (i), the Examiner notes that the primary power source (120) consists of a battery that are fully capable of being removable and replaceable. For example, when a battery loses power the old battery can be removed and replaced by a new battery. Additionally, the battery is stored separately in different housing from the capacitors and injector system (Fig 1, 7; col 5, Ins 30-50). The Applicant has additionally not structurally defined what constitutes 'external' from the injection device. The metes and bounds of the limitation 'external charging device

removably coupled' includes a charging device, ie a battery, that is external to, ie situated outside or apart from, the injection device, ie the capacitor, drive system, and medicament reservoir, and is removably coupled, ie by physically placing/removing the battery from connection with the capacitors. The Applicant in the instant case has not structurally defined the metes and bounds of the injection device, such as the injection device's housing. The Examiner strongly recommends further structurally defining the scope of the injection device, the separate nature of the charging device in relation to the injection device. Additionally, the Examiner notes that the device of Mulhauser et al is fully capable of having an external battery placed in connection with the capacitors to charge the capacitors, and then removing the battery from connection with the capacitors, and then discharging the charge given to the capacitors from the battery in use of the device. The rejection is maintained.

14. In response to the Applicants argument (ii), the Examiner again notes that the Applicant has not structurally defined the metes and bounds as to what constitutes an external charging device. The Examiner has taken the position that an external charging device is fully met by Avarhami et al's source (212; Fig 9; col 21, Ins 26-49). The source (212) is external and removably connected to the injection device, which may be considered to be the reservoir patch (74), electrode drive system (120) and capacitor (216), in that the source (212) is removably detachable from the capacitor through switch (214) and is thus external and separated the circuitry of the injector device when the switch is open. When the switch is closed, the external charging source charges the capacitor, then the switch is opened removing the external charging

source from the injection device, and the capacitor fires powering the drive system and the injection (col 21, lns 41-49). Additionally, the Examiner notes that the injector device is solely powered by the capacitor (216). The power source (212) does not at any time power the injection. The power source only charges the capacitor which in turn powers the injection device. The Examiner strongly recommends structurally defining the injection device, ie its housing, and its relation, specifically its separate status, to the external power source. The rejection is maintained.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767

/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767